

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Original) A pharmaceutical composition comprising an alpha 1-antitrypsin (AAT), a stabilizing carbohydrate, a surfactant and an antioxidant, wherein the AAT is a native AAT, a recombinant AAT, or an AAT variant.
2. (Original) The composition of claim 1, wherein the composition is in a form suitable for administration to a patient via inhalation therapy.
3. (Original) The composition of claim 2, wherein the composition is formulated as a powder.
4. (Original) The composition of claim 2, wherein the composition is formulated as a liquid that can be nebulized.
5. (Original) The composition of claim 1, wherein the AAT is a native AAT.
6. (Original) The composition of claim 1, wherein the AAT is a recombinant AAT.
7. (Original) The composition of claim 1, wherein the AAT is an AAT variant.
8. (Original) The composition of claim 1, wherein the AAT is glycosylated.
9. (Original) The composition of claim 1, wherein the AAT is unglycosylated.
10. (Original) The composition of claim 1, wherein the stabilizing carbohydrate is selected from the group consisting of lactose, sucrose, trehalose, raffinose, maltodextrin and mannitol.
11. (Original) The composition of claim 10, wherein the stabilizing carbohydrate is trehalose.
12. (Original) The composition of claim 1, wherein the antioxidant is selected from the group consisting of methionine, glutathione, cysteine, ascorbic acid and N-acetyl cysteine.
13. (Original) The composition of claim 3, wherein the AAT, carbohydrate, surfactant and antioxidant are present in amounts such that if the powder is solubilized in aqueous solution for administration to a patient the AAT concentration is 1-100 mg/ml, the carbohydrate concentration is 1-5% (w/v), the surfactant concentration is 0.01-0.5% (w/v), and the antioxidant concentration is 1-10 mM.
14. (Original) The composition of claim 13, wherein the AAT concentration is 10-50 mg/ml.
15. (Original) The composition of claim 4, wherein the AAT concentration is 1-100 mg/ml,

the carbohydrate concentration is 1-5% (w/v), the surfactant concentration is 0.01-0.5% (w/v), and the antioxidant concentration is 1-10 mM.

16. (Original) The composition of claim 15, wherein the AAT concentration is 10-50 mg/ml.

17. (Original) The composition of claim 3, further comprising a buffer and wherein (a) the carbohydrate is trehalose and the antioxidant is methionine; and (b) the AAT, trehalose, surfactant and methionine are present in amounts such that if the powder is solubilized in aqueous solution for administration to a patient (i) the AAT concentration is 10-50 mg/ml, (ii) the trehalose concentration is 10-50 mg/ml, (iii) the surfactant concentration is 0.01-0.5% (w/v), and (iv) the methionine concentration is 1-10 mM.

18. (Original) The composition of claim 4, further comprising a buffer and wherein (a) the AAT concentration is 10-50 mg/ml; (b) the carbohydrate is trehalose and its concentration is 10-50 mg/ml; (c) the surfactant concentration is 0.01-0.5% (w/v); and (d) the antioxidant is methionine and its concentration is 1-10 mM.

19. (Original) A pharmaceutical composition, comprising a recombinant alpha 1-antitrypsin (AAT), a stabilizing carbohydrate and at least one additional stabilizing agent selected from the group consisting of a surfactant and an antioxidant, wherein the AAT/carbohydrate ratio (weight:weight) is 1:1 to 5:1, and further wherein the AAT is a native AAT, a recombinant AAT, or an AAT variant.

20. (Original) The composition of claim 19, wherein the ratio is 1:1 to 2:1.

21. (Original) The composition of claim 19, wherein the stabilizing carbohydrate is trehalose.

22. (Original) The composition of claim 19, wherein the composition comprises the surfactant.

23. (Original) The composition of claim 19, wherein the composition comprises the antioxidant.

24. (Original) The composition of claim 19, wherein the composition comprises both the surfactant and the antioxidant.

25. (Original) The composition of claim 24, wherein the surfactant is Polysorbate 80 and the antioxidant is methionine.

26. (Original) The composition of claim 19, wherein the composition is formulated as a solid.

27. (Original) The composition of claim 19, wherein the composition is formulated as a liquid.

28. (Original) The composition of claim 1, wherein the AAT is a native AAT.

29. (Original) The composition of claim 1, wherein the AAT is a recombinant AAT.

30. (Original) The composition of claim 1, wherein the AAT is an AAT variant.

31. (Original) The composition of claim 1, wherein the AAT is glycosylated.

32. (Original) The composition of claim 1, wherein the AAT is unglycosylated.

33-68. (Canceled)